California Medical Device Safety Notification

Notification Name
Medtronic Issues Four Medical Device Notifications Regarding SynchroMed Implantable Infusion System

Notification Date	Notification Details	Safety Issues
06/26/13	Medtronic, Inc. of Minneapolis, MN issued customer notification letters in June 2013 for four separate problems with the Medtronic SynchroMed Implantable Infusion System. Three of the notifications concerned field corrections with the pump. The fourth related to the voluntary removal of Sutureless Connector (SC) Catheters used with the system. The four notifications have been classified by the FDA as Class I recalls.	1. *Pump Priming Bolus Procedure:* *There is the potential for overdose or under-dose while performing the priming bolus procedure.* 2. *Electrical Shorting in Pump:* *There is potential for a short circuit within a feed-through in the pump which could present as a motor stall or alarm/reset.* 3. *Refill Procedure Update:* *This update is a continuation of the 2011 notification. New labeling was provided to reduce the potential for pocket fill (inadvertent injection of prescription drugs) during a refill procedure.* 4. *SC Catheter Removal:* *The SC Catheter has been redesigned to reduce the potential for occlusion. Catheters with a **Use by Date** of August 14, 2014 or sooner are no longer recommended for use.*

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/Safety/Recalls/ucm359069.htm